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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LAVARIAS, ARNEL C	
ART UNIT	**PAPER NUMBER**
2872	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/804,522	JOHNSON, PAUL E.	
	Examiner	Art Unit	
	Amel C. Lavarias	2872	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendments to Claims 1, 7, 11, and 14 in the submission dated 9/26/05 are acknowledged and accepted.

2. The addition of Claims 21-26 in the submission dated 9/26/05 is acknowledged and accepted.

Response to Arguments

3. The Applicant argues that, with respect to newly amended Claims 1, 7, and 14 (as well as Claims 2-6, 8-13, 15-20, which depend on Claims 1, 7, and 14), the combined teachings of Maekawa et al. and McDermott fail to teach or reasonably suggest an illumination device and a detection element for use in a flow particle detection device, the device and element including a detector for detecting fluorescent light from the flow stream resulting from the light from the LED illumination source. After particular consideration of the Maekawa et al. reference, the Examiner agrees, and respectfully withdraws the rejections in Sections 3-8 of the Office Action dated 4/27/05. However, upon further consideration, a new ground(s) of rejection is made in view of Hoffman et al. (U.S. Patent No. 6813017).

4. Claims 1-26 are now rejected as follows.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-2, 6-8, 13, 21, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maekawa et al. (U.S. Patent No. 5644388), of record, in view of Hoffman et al. (U.S. Patent No. 6813017) and McDermott (U.S. Patent No. 5898267), of record.

Maekawa et al. discloses an illumination device and a detection element for use in a flow particle detection device, such as in a flow cytometer (See Figures 1, 3, 5, 6, 9; col. 3, line 56-col. 5, line 62), comprising a laser (See 3a in Figure 5; 3 in Figure 9) for providing light at a selected wavelength; an optical element (See 3, 21 in Figure 9) for collecting light from the laser and concentrating the selected light at a selected volume within a flow sample stream (See 1, 2 in Figure 9); and a detector for detecting fluorescent light from the flow stream resulting from the light from the laser illumination source (See for example 12, 10 in Figure 9). Maekawa et al. also discloses the optical element comprising a focusing element (See 21 in Figure 9). Additionally, Maekawa et al. discloses a particle detection apparatus, such as a flow cytometer (See Figures 1, 3, 5, 6, 9; col. 3, line 56-col. 5, line 62), comprising equipment for passing the sample stream through the flow zone (See 1, 2 in Figures 1, 3, 5, 6, 9), an illumination device (See 3a in Figure 5; 3 in Figure 9), and a detector assembly (See 14, 12, 10 in Figure 9), which

includes a detector (See 14, 12, 10, 11 in Figure 9) that detects fluorescent light emitted from illuminated target particles within the flow zone as a result of illumination from the illumination device, wherein the illumination device consists substantially of a laser for providing light at a selected wavelength and an optical element (See 3, 21 in Figure 9) for collecting light from the laser and concentrating the collected light at a selected volume within a flow sample stream (See for example 1, 2 in Figure 9). Maekawa et al. also discloses the optical element comprising a focusing element (See 21 in Figure 9); and the detector assembly also including means for detecting the presence of illuminated target particles within the flow zone (See 14, 12, 10 in Figure 9; col. 4, lines 24-32; col. 13, line 21-col. 14, line 8); and measuring properties of the particles based upon fluorescent light emitted from the particles as a result of illumination from the illumination device (See 11, 12, 10 in Figure 9; col. 6, lines 39-46; col. 7, lines 9-15; col. 13, line 61-col. 14, line 35).

Maekawa et al. discloses the invention as set forth above, except for the laser being an LED source and the optical element, such as a collecting element having a small focal length, collecting nearly all the light from the LED. However, it is well known and conventional in the art to utilize LED illumination sources in place of or in addition to laser illumination sources in flow cytometer systems. For example, Hoffman et al. teaches a conventional flow cytometer system (See for example Figures 1-3, 9), wherein one or more LED illumination sources are utilized to illuminate the flow stream of a flow cytometer (See for example 124 in Figures 1-3). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the laser illumination source be an LED source, as taught by Hoffman et al., in the device and

apparatus of Maekawa et al., for the purpose of reducing the overall size, cost, and weight of the optical system, as well as reducing power consumption requirements and increasing the life of the sources. The combined teachings of Maekawa et al. and Hoffman et al. lack the optical element, such as a collecting element having a small focal length, collecting nearly all the light from the LED. However, it is well known and conventional in the art for LED's to include an integrated, encapsulating optical element through which all the light generated from the LED must pass through, prior to being routed to another location. For example, McDermott teaches a conventional LED element (See for example Figures 1, 3-4, 6, 8-9), wherein the LED element (See for example 1 in Figure 3) is totally encapsulated by an element (See 11 in Figures 1, 3), whereby light generated by the LED element must pass through the encapsulating element. Thus, this encapsulating element collects most, if not all, of the light generated by the LED element and routes this light. In addition, the encapsulating element has an appropriate and relatively short focal length to collimate the incident light, producing an outgoing collimated beam of light. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the element, such as a collecting element having a small focal length, in the device and apparatus of Maekawa et al. and Hoffman et al., collect nearly all the light from the LED, as taught by McDermott, to take advantage of the more compact, more precise, and more efficient design of the LED provided by McDermott, thus increasing light throughput.

7. Claims 4, 10-11, 14, 18, 20, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maekawa et al. in view of Hoffman et al. and McDermott as applied to

Claims 1, 7, 21 above, and further in view of Martin et al. (U.S. Patent No. 4573796), of record.

Maekawa et al. in view of Hoffman et al. and McDermott discloses the invention as set forth above in Claims 1, 7, 21, except for the LED providing light at two selected wavelengths. However, Martin et al. teaches a multiple source flow cytometer apparatus (See Figure 1) wherein two sources (See 10 and 12 in Figure 1) with two different wavelengths (See col. 3, line 62-col. 4, line 20) are used to illuminate the particle flow (See 16 in Figure 1) to induce fluorescence and light scattering. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate sources providing light at different wavelengths, as taught by Martin et al., in the particle detection apparatus as disclosed by Maekawa et al. in view of Hoffman et al. and McDermott. One would have been motivated to do this to provide source illumination for multiple dyes that may be bound to the particles in the sample flow and to additionally eliminate background noise due to cross-interference in multiple light sources measurements.

8. Claims 15, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maekawa et al. in view of Hoffman et al. and McDermott, and further in view of Martin et al.

Maekawa et al. in view of Hoffman et al. and McDermott, and further in view of Martin et al, discloses the invention as set forth above in Claims 1, 7, 14, 21, 23, except for the detector assembly comprising two detectors for detecting emitted light at two wavelengths. However, Martin et al. teaches a multiple source flow cytometer apparatus

(See Figure 1) wherein two or more detectors (See for example 24, 26, 32, 34 in Figure 1) are used to detect the fluorescence and scattered light from the sample particle flow (See 16 in Figure 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate multiple detectors for detecting emitted light at two wavelengths, as taught by Martin et al., in the particle detection apparatus as disclosed by Maekawa et al. in view of Hoffman et al. and McDermott, and further in view of Martin et al. One would have been motivated to do this to detect fluorescence and scattered light at multiple wavelengths from multiple dyes attached to the particles in the sample particle flow, thus increasing the detection capability, range, and sensitivity of the system.

9. Claims 12, 16-17, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maekawa et al. in view of Hoffman et al. and McDermott, and further in view of Martin et al.

Maekawa et al. in view of Hoffman et al. and McDermott, and further in view of Martin et al., discloses the invention as set forth above in Claims 1, 7, 10-11, 14-15, 21, 23-24, except for the sample stream including two fluorescent dyes that emit at two different wavelengths. However, Martin et al. teaches a multiple source flow cytometer apparatus (See Figure 1) wherein the particles in the sample particle flow are stained with two or more fluorescent dyes (See col. 3, line 62-col. 4, line 20), each dye fluorescing at different wavelengths. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide multiple fluorescent dyes on the particles in the sample particle flow, as taught by Martin et al., in the particle

detection apparatus as disclosed by Maekawa et al. in view of Hoffman et al. and McDermott, and further in view of Martin et al. One would have been motivated to do this to detect multiple components of the particles in the sample particle flow, thus increasing the detection capability, range, and sensitivity of the system.

10. Claims 3, 9, 19, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maekawa et al. in view of Hoffman et al. and McDermott, and further in view of Martin et al.

Maekawa et al. in view of Hoffman et al. and McDermott, and further in view of Martin et al., discloses the invention as set forth above in Claims 1, 7-8, 14, 18, 21, except for the collecting element being a ball lens. However, it is well known and conventional in the art to utilize ball lenses as optical elements to provide focusing and collimating functions within an optical system. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a ball lens to collect the illumination light from the light source since it is well known in the art of optics and lasers to use a ball lens to collect and collimate light from light emitting diodes and laser diodes. One would have been motivated to do this to increase the volume of the particle flow that is irradiated and therefore to increase the fluorescence collection efficiency.

11. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maekawa et al. in view of Hoffman et al. and McDermott as applied to Claim 1 above, and further in view of Ross et al. (U.S. Patent No. 5877863), of record.

Maekawa et al. in view of Hoffman et al. and McDermott discloses the invention as set forth above in Claim 1, except for the LED being a side-emitting lensless LED. However, Ross et al. teaches a photometric diagnostic instrument (See for example Figure 1 or Figure 2) wherein the light sources (See 20 in Figure 1 or Figure 2) utilized are surface mount lensless LEDs (See col. 4, line 66-col. 5, line 16; Figure 7). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate lensless LEDs as the light source, as taught by Ross et al., in the LED illumination source device as disclosed by Maekawa et al. in view of Hoffman et al. and McDermott. One would have been motivated to do this to provide a more uniformly diverging source for illumination prior to focusing using a lens.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arnel C. Lavarias whose telephone number is 571-272-2315. The examiner can normally be reached on M-F 9:30 AM - 6 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Drew Dunn can be reached on 571-272-2312. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Group Art Unit 2872
11/29/05